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| 10/089,887 | 03/29/2002 | Bruce M. Boman | 1657/1022 | 2568 |

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EXAMINER

VANDERVEGT, FRANCOIS P

| | |
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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1644

DATE MAILED: 02/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,887

Applicant(s)

BOMAN ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-26, 29, 31-33, 35-42 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27, 28, 30, 34, 43 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1644

DETAILED ACTION

This application is a continuation of U.S. Application Serial Number PCT/US00/21606.

Claims 1-45 are currently pending.

Election/Restrictions

1. Applicant's election of Group 114, claims 27-28, 30, 34 and 43-44 as they read upon SEQ ID NO: 46, in the reply filed on November 10, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-26, 29, 31-33, 35-42 and 45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 10, 2004.

Claims 27-28, 30, 34, 35-42 and 45 are withdrawn TO THE EXTENT THAT THEY READ UPON NUCLEIC ACID MOLECULES OTHER THAN SEQ ID NO: 46 from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 10, 2004.

Accordingly, claims 27-28, 30, 34, and 43-44 are the subject of examination in the present Office Action ONLY TO THE EXTENT THAT THEY READ UPON SEQ ID NO: 46.

For the purposes of the present Office Action, claim 30 is being read as bodily incorporating the antibody of claim 18 or 19, however claims 18 and 19 are not being examined on their merits.

Claim Objections

2. Claim 30 is objected to because of the following informalities: line 1 of the claim recites "determining the presence of absence of a polypeptide." The recitation appears to be a typographical error and the claim should be amended accordingly.

Claim 34 is objected to because of the following informalities: there is no period at the end of the claim. Each claim must be readable as a complete, single sentence ending with a period.

Appropriate correction is required.

Art Unit: 1644

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 27-28, 30, 34 and 43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are most broadly drawn to the detection of a putative polypeptide that may be encoded by SEQ ID NO: 46, determining the phenotype of a cell based upon differential expression of the putative polypeptide encoded by SEQ ID NO: 46, or detecting a tumor based upon expression of the putative polypeptide encoded by SEQ ID NO: 46.

The putative peptide has been reverse transcribed from the cDNA sequence of SEQ ID NO: 46. SEQ ID NO: 46 was isolated from a library obtained from HCT116 cells, a cultured human colon cancer cell line (pages 96 and 100-101 of the specification, for example). The cDNA was identified in the specification as CATX-15 (SEQ ID NO: 46), is 3032 nucleotides in length and "appears to be a complete cDNA" (page 100, line 24 for example). The isolated cDNA was subjected to analysis to predict open reading frames within the sequence and an open reading frame encoding for a putative 246 amino acid polypeptide (SEQ ID NO: 47) was identified (paragraph bridging pages 100-101 for example). A 246 amino acid polypeptide requires only a 741 nucleotide long (including a stop codon) mRNA encoding it. There is no indication in the specification, however, that the actual polypeptide of SEQ ID NO: 47 has ever been expressed from the cDNA or isolated from a natural tissue source, nor is there any disclosure of any other polypeptide sequence being identified from the cDNA of SEQ ID NO: 46. Accordingly, Applicant has not demonstrated that any polypeptide encoded by SEQ ID NO: 46, other than the putative SEQ ID NO: 47 was in Applicant's possession at the time the application was filed.

Furthermore, the claims are drawn to methods of detecting a polypeptide encoded by SEQ ID NO: 46 in order to phenotype a cell or to differentiate a cell from a "normal" cell. The instant specification demonstrated the presence of SEQ ID NO: 46 in a single clonal line of human cancer cells and its absence in normal colonic epithelial cells isolated from a single subject (table 2 for example). However, no polypeptide encoded by SEQ ID NO: 46, including the putative SEQ ID NO: 47, has been demonstrated to be present or absent in any type of cell. There is no indication that a polypeptide

Art Unit: 1644

encoded by SEQ ID NO: 46, or a subsequence thereof, was expressed in the colonic cancer cells, not expressed in the normal colonic epithelial cells, or differentially expressed between any cell types. Further, because there is no evidence that a polypeptide encoded by SEQ ID NO: 46 even exists, there is no evidence that antibodies to such a polypeptide have been generated. The recitation of antibodies for detecting the polypeptide in cells in the instant claims is based solely upon the identification of a putative open reading frame within the sequence of SEQ ID NO: 46, not upon the isolation of any actual polypeptide product.

Vas-Cath Inc. v. Mahurkar ((CAFC, 1991) 19 USPQ2d 1111) clearly states that "Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See *Vas-Cath* at page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see *Vas-Cath* at page 1115).

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, ((CAFC, 1993) 25 USPQ 2d 1601) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, ((CAFC, 1991) 18 USPQ2d 1016).

The sole support for the claimed method is in Table 2 and at the paragraph bridging pages 100-101 of the instant specification showing that a nucleic acid molecule reversed transcribed to yield SEQ ID NO: 46 was present in a single clonal human colon cancer cell line but was not present in cells isolated from a single normal colonic epithelium tissue. This is insufficient to support the recitation in the claims of methods of determining the presence or absence of a polypeptide encoded by SEQ ID NO: 46 using antibodies to the polypeptide, determining the phenotype of a cell based upon expression of a polypeptide encoded by SEQ ID NO: 46 or detecting differential expression of a polypeptide encoded by SEQ ID NO: 46 in a cell as provided by the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

4. Claims 27-28, 30, 34, 35-42 and 45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Art Unit: 1644

The claims are most broadly drawn to the detection of a putative polypeptide that may be encoded by SEQ ID NO: 46, determining the phenotype of a cell based upon differential expression of the putative polypeptide encoded by SEQ ID NO: 46, or detecting a tumor based upon expression of the putative polypeptide encoded by SEQ ID NO: 46.

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Art Unit: 1644

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 27-28 and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 is ambiguous and indefinite in the recitation of "determining the phenotype of a cell...relative to a normal cell." It is unclear what the "cell" and "normal cell" refer to. Are the cells specific to a particular species? Is the "cell" possibly another type of "normal" cell from the subject organism?

Claim 27 is ambiguous and indefinite in the recitation of "wherein the polypeptide is differentially expressed by at least a factor of two." The claim lacks a step correlating the differential expression to a particular phenotype. Is expression in the "normal cell" two times higher or lower than the unknown cell?


Conclusion


6. No claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. 
Patent Examiner
January 31, 2005


PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER

2/1/05